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Patent Group
ROPES & GRAY
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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/646,985

Applicant(s)

HAMMOND ET AL.

Examiner

Suryaprabha Chunduru

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicants' response to the office action filed on July 22, 2005 has been entered.
2. Claims 1, 3-11 are pending.

Status of the Application

3. Applicants' response to the office action is fully considered and found not persuasive. All arguments have been fully considered and thoroughly reviewed, but are deemed persuasive in part for the reasons that follow. This action is made FINAL.
4. The following are the rejections made in the previous office action:

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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A. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Hotz et al. (Mol. Biochem. Parasitology, Vol. 75, pages 1-14, 1995).

Claim interpretation : In the instant specification, a "population" of DNA molecules is defined as more than one DNA molecule, accordingly in the following rejection plasmid DNAs (more than one) are considered as a population. Further 5' over hangs are interpreted as 5' end of the DNA molecule having a restriction enzyme sequence over hang.

Hotz et al. teach a method of claim 1, for removing the 3'-untranslated region (3'-UTR) of a population of DNA molecules, wherein each DNA molecule in said population of DNA molecules comprises an open reading frame and a 3'-untranslated region (see page 3, Fig. 1, indicating chlorophenicol acetyltransferase (CAT) gene (coding region) and 3'-UTR, also see page 2, col. 2, paragraph 2.1, indicates that the transient transfection plasmids, control plasmid, THT plasmids each comprises a CAT gene and 3'UTR) said method comprising

(a) providing a population of DNA molecules, each of said DNA molecules terminating at its 5' end in an overhang (see page 2, col. 2, paragraph 2.1, page 3, col. 1, line 1-13 indicates the DNA molecules amplified by using primer with restriction sites for ApaI (G/GGCCC or GGGCC/C) and XhoI (C/TCGAG) generates 5' end over hangs and 3' end blunt end);

(b) treating each of said DNA molecules first with a 3'-5' exonuclease and then with a single-stranded nuclease under conditions that allow removal of said 3'-untranslated region (see page 3, col. 1, line 8-16, page 4, Fig. 2 B. indicates 3'UTR deletions).

With regard to claim 2, Hotz et al. teach that said 3'-5' exonulcease is exonuclease III (see page 3, line 10-11);

With regard to claim 3, Hotz et al. teach that said nuclease is Mung bean nuclease (see page 3, line 10-11). Accordingly Hotz et al. meets the limitations in the instant claims.

B. Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Treco et al. (USPN. 6,063,630).

Treco et al. teach a method of claim 1, for removing the 3'-untranslated region (3'-UTR) of a population of DNA molecules, wherein each DNA molecule in said population of DNA molecules comprises an open reading frame and a 3'-untranslated region (see col. 17, line 13-20, indicates Hind III digests DNA fragments, each comprises a neo gene open reading frame and a poly A at 3' end, see Fig. 2 description) said method comprising

(a) providing a population of DNA molecules (Hind III digested molecules), each of said DNA molecules terminating at its 5' end in an overhang and at its 3' end blunt end (see col. 17, line 6-20, indicating 5' overhangs and 3' end blunt end) ;

(b) treating each of said DNA molecules first with a 3'-5' exonuclease and then with a single-stranded nuclease under conditions that allow removal of said 3'-untranslated region (poly A region) (see col. 17, line 13-45).

With regard to claim 2, Treco et al. teach that said 3'-5' exonuclease is exonuclease III (see col. 17, line 18-28);

With regard to claim 3, Treco et al. teach that said nuclease is Mung bean nuclease (see col. 17, line 28-29). Accordingly Treco et al. meets the limitations in the instant claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hotz et al. (Mol. Biochem. Parasitology, Vol. 75, pages 1-14, 1995) in view of Szostak et al. (USPN. 6,214,553, reference taken from the IDS submitted by the Applicants).

Hotz et al. teach a method of claims 4-11, for removing the 3'-untranslated region (3'-UTR) of a population of DNA molecules, wherein each DNA molecule in said population of DNA molecules comprises an open reading frame and a 3'-untranslated region (see page 3, Fig. 1, indicating chlorophenicol acetyltransferase (CAT) gene (coding region) and 3'-UTR, also see page 2, col. 2, paragraph 2.1, indicates that the transient transfection plasmids, control plasmid, THT plasmids each comprises a CAT gene and 3'UTR) said method comprising

(a) providing a population of DNA molecules, each of said DNA molecules terminating at its 5' end in an overhang (see page 2, col. 2, paragraph 2.1, page 3, col. 1, line 1-13 indicates the DNA molecules amplified by using primer with restriction sites for ApaI (G/GGCCC or GGGCC/C) and XhoI (C/TCGAG) generates 5' end over hangs and at its 3' end blunt end);

(b) treating each of said DNA molecules first with a 3'-5' exonuclease and then with a single-stranded nuclease under conditions that allow removal of said 3'-untranslated region (see page 3, col. 1, line 8-16, page 4, Fig. 2 B. indicates different 3'UTRs deletions).

Hotz et al. also teach that said 3'-5' exonuclease is exonuclease III (see page 3, line 10-11); and said nuclease is Mung bean nuclease (see page 3, line 10-11).

However, Hotz et al. did not specifically teach removal of stop codon, cDNA produced by reverse transcription and said population of DNA molecules comprising at least 10 DNA molecules to 10^6 DNA molecules.

Szostak et al. teach a method of claim 4, for selection of desired RNA and screening cDNA libraries, wherein Szostak et al. disclose that the method comprises generating a cDNA library, ligating a protein acceptor, and testing the interaction with particular molecules, wherein stop codons and 3-UTR regions are avoided by removal of stop codons and 3-UTR from the DNA sequences (see col. 3, line 16-26, col. 41, line 59-67, col. 42, line 1-9).

With regard to claim 5, Szostak et al. also teach that the DNA molecule is a cDNA produced by reverse transcription from an RNA sequence (see col. 4, line 27-31) and

With regard to claims 6-11, Szostak et al. teach that a population of DNA molecules comprises one or more DNA molecules, that includes more than 10^9 to more than 10^{14} DNA molecules (see col. 39-43, line 63-67, col. 5, line 1-3).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to modify the method for removing 3'UTR as taught by Hotz et al. with a step of including removal of stop codons, and an addition of cDNA library comprising more than 10^{14} DNA molecules as taught by Szostak et al. for the purpose of screening cDNA

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libraries because Szostak et al. explicitly taught that “for screening cDNA libraries the stop codons and 3’-UTR are avoided if desirable (see col.42, line 3-9). Therefore one skilled in the art would have been motivated to combine the method of removal of 3’UTR as taught by Hotz et al. with a step of removal of stop codons and inclusion of cDNA libraries as taught by Szostak et al. because the ordinary artisan would have a reasonable expectation of success that inclusion of said parameters would result in screening of large number of cDNAs that would aid in identifying new genes.

New Grounds of Rejections necessitated by Amendment

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites “DNA molecules terminating at its 5’ end in a 3’ ***DNA chain over hang*** which is unclear and indefinite whether the recited “3’ DNA chain over hang” refers to a complementary DNA strand of a double stranded DNA molecule at its 5’ end or does it refers to the single strand DNA molecule having 5’ end. If the population of DNA molecules are single stranded, each single stranded DNA molecule terminating at its 5’ end in a 3’ DNA overhang, the meets and bounds of the claim 1 are unclear because 5’ end terminates with a 5’ over hang and not with a 3’ over hang.

Response to arguments:

8. With regard to the rejection made in the previous office action under 35 USC 102(b) as anticipated by Hotz et al., Applicant's arguments filed on July 22, 2005 have been fully considered but they are not persuasive. Applicants argue that Hotz et al. did not teach providing DNA molecules each terminating at 5' end in a 3' overhang and at its 3' end in a blunt end, and sequential treatment of said DNA molecules with exonuclease III and then with a single-stranded nuclease. Applicants' amendment and arguments are fully considered and found unpersuasive.

First, the instant claims are in "comprising" open format, thus any additional steps are permissive. The step of making use of restriction sites to provide DNA molecules having 5' end overhang and 3' end blunt is permissive as an additional step. Further, Hotz et al. teach sequential treatment of DNA molecules with exonuclease III and then with a single-stranded nuclease to create unidirectional 3'UTR deletions (see page 3, col. 1, line 1-15). Thus Hotz et al. does teach the limitations in claims 1 and 3 and therefore the rejection is maintained for claims 1 and 3.

9. With regard to the rejection made in the previous office action under 35 USC 102(e) as anticipated by Treco et al., Applicant's arguments filed on July 22, 2005 have been fully considered but they are persuasive. The rejection is withdrawn in view of persuasive arguments drawn to exonucleolytic digestion at each end (which is not a unidirectional deletion).

10. With regard to the rejection made in the previous office action under 35 USC 103(a) as being obvious over Hotz et al. in view of Szostak et al., Applicant's arguments filed on July 22, 2005 have been fully considered but they are not persuasive. Applicants argue that Hotz et al. teach removal of 5' overhangs at 5' end because Hotz et al. used Xho I digestion to generate 5' overhang and provides New England Biolabs catalog for exonuclease III and argue that Hotz et

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al. does not teach the instant invention and the combination of Hotz et al. in view of Szostak et al. does not make the instant claims obvious. Applicants' arguments are fully considered and found unpersuasive. First, Hotz et al. used two restriction sites to provide 5' over hang and a 3' blunt end comprising DNA molecules. Second, Hotz et al. teach unidirectional deletions of 3' UTR and not a 5'UTR deletion. Thus exonuclease III used in making unidirectional 3'UTR deletions inherently teaches that the 5' end is made resistant to exonuclease digestion. Therefore Hotz et al. does teach removal of 3' UTR and the combination of Hotz et al. in view of Szostak et al. does make the instant claims obvious as discussed in the previous office action.

Conclusion

No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Suryaprabha Chunduru
Patent Examiner
Art Unit 1637


JEFFREY FREDMAN
PRIMARY EXAMINER

9/14/14